DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 18 2012

Re: PRADAXA
Docket No.: FDA-2011-E-0117

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,087,380, filed by Boehringer Ingelheim Pharma GmbH & Co. KG, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for PRADAXA (dabigatran etexilate mesylate), the human drug product claimed by the patent.

The total length of the regulatory review period for PRADAXA (dabigatran etexilate mesylate) is 2,633 days. Of this time, 2,449 days occurred during the testing phase and 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 6, 2003.

   The applicant claims August 7, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 6, 2003, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: April 19, 2010.

   The applicant claims December 15, 2009, as the date the new drug application (NDA) for PRADAXA (NDA 22-512) was initially submitted. However, FDA records indicate that NDA 22-512, received December 15, 2009, was incomplete. FDA refused to file this application and notified the applicant of this fact by letter dated February 12, 2010. The completed NDA was then submitted on April 19, 2010, which is considered to be the NDA initially submitted date.

3. The date the application was approved: October 19, 2010.

   FDA has verified the applicant's claim that NDA 22-512 was approved on October 19, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Wendy A. Petka
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